

REMARKS

By this amendment, claims 1, 17, and 21 are amended, claims 2-5, 18, 22, and 23 are cancelled, and claims 24-26 are added. Claims 1, 6-17, 19-21, 24-26 are now pending. Support for the amendments and new claims can be found, *inter alia*, in the drawings as well as in paragraphs 29 and 38-49. Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

Rejections Under 35 U.S.C. §103

The Office Action rejects claims 1-23 under 35 U.S.C. §103(a) over WO 0078286 to WU ("*Wu*") in view of U.S. Patent No. 6,296,156 to Lasserre et al. ("*Lasserre*"). The rejection is respectfully traversed for the following reasons as well as the arguments presented in earlier responses, which are incorporated herein by reference.

Present independent claim 1 recites, *inter alia*: "said aerosol canister having a rolled neck or full rollover rim in contact with said rubber valve gasket." Present independent claim 17 recites, *inter alia*: "forming a rolled neck or full rollover rim on a canister." Present independent claim 21 recites, *inter alia*: "providing a canister with a rolled neck or full rollover

rim; washing a valve provided with a rubber gasket for use in connection with said canister and crimping said valve to said canister.” As noted in the specification, the recited rolled neck or full rollover rim are used because the inventors have discovered that the cutting edge on a canister can damage or compress the surface of the gasket, thereby facilitating the migration of components from the rubber to the solution. *See e.g.* Para. 46.

Wu discloses a can with a standard cut edged opening used in a metered dose inhaler for the delivery of medicinal aerosol products. *Wu* does not however appreciate the problems overcome by the present invention. *See e.g.* p. 3, ll. 3-7 (“the problem of chemical degradation in steroid solution aerosol products has been poorly understood.”). *Wu* teaches to improve the chemical stability of a 20-keto steroid by utilizing a container provided with a non-metal interior surface, so as to avoid the contact of the active ingredient with metal surfaces.

Wu does not raise at all the problem of the migration of components from the rubber of the gasket to the solution. Further, as noted by the Examiner, *Wu* does not teach or suggest a rolled neck canister. *Wu* cannot therefore by itself obviate the pending claims.

Lasserre, in turn, teaches a spring-like connection for mounting a valve on a container where the spring is formed by bending the edge of the canister to form a rolled or bent neck that wedges and locks into an annular groove on a cap, the annular groove having a deformable portion. *Lasserre*, col. 5, ll. 3-7. For the following reasons, however, Applicant respectfully asserts that *Lasserre* cannot be combined with *Wu* to overcome the deficiencies of *Wu* with respect to the presently recited claims.

As stated by Federal Circuit this past March, an obviousness analysis relies on the “motivation-suggestion-teaching” test and “asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge

reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Further, “Most inventions arise from a combination of old elements and each element may often be found in the prior art. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole.” *Id.* at 986 (internal citation omitted).

Neither of the prior art references cited by the Examiner teach or suggest the existence of the problem being solved by the present invention, or its solution. Particularly, neither reference recognizes that the gasket can be damaged during connection of the canister to the valve by a sharp end on the canister leading to degradation of the medication in the canister – or in fact even recognize that a degradation has occurred. Applicants’ discovery of this problem provides an unexpected improvement in the operation of medicinal canisters and thus provide a way of improving the art of medicinal aerosol products by protecting a gasket from damage by, for example, “forming a rolled neck or full rollover rim on a canister.” Contrary to the Examiner’s assertions at page 4, para. 1 of the Office Action, there is nothing that would motivate one skilled in the art to look for a device with a rolled neck. In view of this unexpected improvement, Applicants maintain that they are entitled to a patent and respectfully request that the Examiner withdraw the present rejection for obviousness.

In addition, Applicants further traverse the Examiner’s rejection for obviousness on the grounds that the Examiner’s combination of *Wu* with *Lasserre* is improper. The prior art must teach or suggest making a modification to the prior art in order to render a claimed invention obvious. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). In other words, one must be motivated by the prior art to make the modification necessary to arrive at the present invention.

In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991). Absent such motivation, a rejection based on a combination of references is unsupported and any rejection based on such a combination must be withdrawn. *Lasserre* teaches away from combining the references by referring to a crimping assembly as used in *Wu* (col. 1, ll. 50-54) and then noting that such a process damages the device (col. 1, l. 65 to col. 2, l. 2). In other words, *Lasserre* expressly teaches that it is a non-interchangeable alternative to *Wu*. One skilled in the art would not therefore look to combine the references. Further, because neither *Wu* nor *Lasserre* recognize the problem to be solved, one would not pick and choose amongst *Lasserre*'s teachings to pair with *Wu*'s, or vice versa.

Further, independent claim 21 now recites, *inter alia*, "crimping said valve to said canister." *Lasserre* directly teaches away from this act at column 1, line 35 to column 2, line 2, where it refers to damage that a crimping process may allegedly cause. *Lasserre* goes on to teach and claim the non interchangeable alternative of the bent canister neck / deformable annular ring assembly. Thus, *Lasserre* cannot be combined with *Wu*, which teaches crimping, to make the rejection of claim 21. For at least this additional reason, claim 21 (and for similar reasons new claims 24-25) is patentable over the cited combination of references and the prompt removal of this rejection is respectfully requested.

Accordingly, Applicants respectfully request that the obviousness rejection of the pending claims be withdrawn.

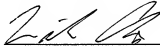
Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited. Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number set forth below.

Any additional fees incident to this Amendment may be charged to Deposit Account No. 08-2665.

DATED this 22nd day of December, 2006.

Respectfully submitted,



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